UNITED STATES DISTRICT COUXRT
SOUTHERN DISTRICT OF NEW YORK

JAMES TONRA, Ph.D., Plaintiff, v. KADMON HOLDINGS, INC., HARLAN W. WAKSAL, M.D., and JOHN RYAN, M.D, Ph.D., Defendants.	Case No. 1:18-cv-09028 (JGK)

MOTION OF DEFENDANTS KADMON HOLDINGS, INC., HARLAN WAKSAL AND JOHN RYAN TO DISMISS PLAINTIFF'S COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(6)

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TABLE OF CONTENTS

PRELIMINARY STATEMENT 1

STATEMENT OF FACTS 3

I. Kadmon and Tonra, Generally 3

II. Tonra's Whistleblower Allegations 4

a. The Biopharmaceutical Business, Generally 4

b. Tonra's Role and Alleged Whistleblower Claims 6

ARGUMENT 10

I. Motion to Dismiss Standard 10

II. Plaintiff Fails to State a Claim for Unlawful Retaliation Under SOX 11

a. SOX, Generally 11

b. Plaintiff Never Engaged in Protected Activity 12

i. Tonra Did Not Identify Conduct that He Believed to Be Illegal 12

ii. Plaintiff Did Not Object to Conduct Relating to Federal Securities Law 13

iii. Plaintiff Did Not Reasonably Believe Kadmon Violated Securities Law 15

III. Plaintiff's New York Labor Law §§ 215 and 740 Claims Are Deficient 17

a. Plaintiff Fails to State an Actionable Section 740 Claim 17

b. Plaintiff's Section 740 Claim Preempts his Section 215 Claim 19

IV. Plaintiff's Claims for Breach of Contract and Related Claims Are Deficient 20

a. The Sought Bonus Does Not Constitute "Wages" Under the New York Labor Law 20

b. Plaintiff's Breach of Contract of Claims Fail as a Matter of Law 21

i. The Sought Bonuses Are Discretionary 21

ii. The 2011 Bonus Claim Is Barred by the Statute of Limitations 22

iii. Plaintiff's Breach of the Covenant of Good Faith and Fair Dealing Should Also Be Dismissed 22

CONCLUSION 23

TABLE OF AUTHORITIES

Cases **Page(s)**

Arrouet v. Brown Bros. Harriman & Co.,
2005 WL 646111 (S.D.N.Y. Mar. 18, 2005) 21, 22

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 10, 11

Barber v. Deutsche Bank Sec., Inc.,
103 A.D.3d 512 (1st Dep't 2013) 21

Barber v. Von Roll U.S.A., Inc.,
2015 WL 5023624 (N.D.N.Y. Aug. 25, 2015) 18

Beach v. Touradji Capital Mgmt., LP,
2014 WL 840409 (Sup. Ct. N.Y. Cnty. Feb. 26, 2014) 21

Bechtel v. Admin. Rev. Bd., U.S. Dep't of Labor,
710 F.3d 443 (2d Cir. 2013) 11

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007) 11

Canstar v. J.A. Jones Const. Co.,
212 A.D.2d 452 (1st Dep't 1995) 22

Collette v. St. Luke's Roosevelt Hosp.,
132 F. Supp. 2d 256 (S.D.N.Y. 2001) 19

Cotrone v. Consol. Edison Co. of N.Y., Inc.,
50 A.D.3d 354 (1st Dep't 2008) 19

Diaz v. Transatlantic Reinsurance Co.,
2016 WL 3568071 (S.D.N.Y. June 22, 2016) 11, 14, 15

Duffy v. RMSCO, Inc.,
34 A.D.3d 1285 (4th Dep't 2006) 20

Fraser v. Fiduciary Trust Co. Int'l,
2009 WL 2601389 (S.D.N.Y. Aug. 25, 2009) 12, 13

Gallas v. Med. Ctr. of Aurora,
2017 WL 2222626 (Dept. of Labor SAROX Apr. 28, 2017) 15

Grieve v. Barclays Capital Sec. Ltd.,
1999 WL 1680654 (Sup. Ct., N.Y. Cnty. Sept. 10, 1999) 21

Gross v. 420 E. 72nd St. Tenants Corp.,
864 N.Y.S.2d 863 (Sup. Ct., N.Y. Cnty. 2008) 22

Kern v. DePaul Mental Health Servs., Inc.,
152 A.D.2d 957 (4th Dep't 1989) 18

Lawrence v. I.B.M. Corp.,
2017 WL 3278917 (S.D.N.Y. Aug. 1, 2017) 14

Leviege v. Vodafone U.S., Inc.,
2017 WL 628506 (Dept. of Labor SAROX Feb. 1, 2017) 16

Lloyd v. Cardiology & Internal Med. of Long Island, PLLC,
847 N.Y.S.2d 902 (Sup. Ct., Nassau Cnty. 2007) 18

Mandavia v. Columbia Univ.,
912 F. Supp. 2d 119 (S.D.N.Y. 2012) 3

Nadkarni v. N. Shore-Long Island Jewish Health Sys.,
21 A.D.3d 354 (2d Dep't, 2005) 18

Namad v. Salomon Inc.,
74 N.Y.2d 751 (N.Y. 1989) 21

Nielsen v. AECOM Tech. Corp.,
762 F.3d 214 (2d Cir. 2014) 15

Ruotolo v. Fannie Mae,
933 F. Supp. 2d 512 (S.D.N.Y. 2013) 3

Truelove v. Ne. Capital & Advisory Inc.,
268 A.D.2d 648 (3d Dep't 2000) 20

Truelove v. Ne. Capital & Advisory, Inc.,
95 N.Y.2d 220 (N.Y. 2000) 20

Welch v. Chao,
536 F.3d 269 (4th Cir. 2008) 12

Wiggins v. ING U.S., Inc.,
2015 WL 8779559 (D. Conn. Dec. 15, 2015) 16

Statutes & Other Authorities

18 U.S.C. § 1514A .... *passim*

21 C.F.R. § 58.1 5

21 C.F.R. § 58.3 5

21 C.F.R. § 312.21 5

21 C.F.R. § 312.23. 5

21 C.F.R. § 312.31 9

21 C.F.R. § 312.32 .... 6, 9

21 C.F.R. § 312.33 .... 6, 9

21 C.F.R. § 312.55 .... 5, 6, 9

Fed. R. Civ. P. 12(b)(6) 1, 10, 23

N.Y. C.P.L.R. § 213 22

N.Y. Labor Law § 193 .... 2, 20, 21

N.Y. Labor Law § 215 17

N.Y. Labor Law § 740 .... *passim*

Defendants Kadmon Holdings, Inc. ("Kadmon" or the "Company"), Harlan Waksal, M.D., and John Ryan, M.D., Ph.D. (together, "Defendants") submit this memorandum of law in support of their motion to dismiss the Amended Complaint ("Complaint" or "Compl.") of plaintiff James Tonra, Ph.D. ("Tonra" or "Plaintiff"), pursuant to Fed. R. Civ. P. 12(b)(6).[1]

PRELIMINARY STATEMENT

Tonra is a former employee of a subsidiary of Kadmon – a biopharmaceutical company engaged in the discovery and development of drug candidates – whose employment was terminated in late September 2017. In the instant action, Tonra alleges that he was terminated in retaliation for engaging in protected activity under the Sarbanes Oxley Act, 18 U.S.C. § 1514A ("SOX"), and New York Labor Law § 740 ("Section 740"). In addition, he contends that during his employment, he was not paid certain bonuses to which he claims entitlement.

Plaintiff's claims are universally deficient and should be dismissed with prejudice. Initially, his SOX claim is entirely contrived: Tonra contends that, on the day prior to his termination, he reported the initial results of an animal study on a drug candidate, tesevatinib, that was (and still is) in clinical (human) trials before the Food and Drug Administration ("FDA"). As best as can be determined from deciphering his Complaint, Tonra appears to claim that he did not object to any actual violation of law, but rather he believed that at some point in the future, Kadmon might fail to report the results of this animal study to the FDA.

Setting aside that Kadmon did timely report this study, and that Tonra's own e-mails reflect he did not believe reporting was required for months (or longer), his SOX claim is completely defective. In the first instance, Tonra did not object to anything; his own pleadings

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[1] True and correct copies of exhibits ("Ex. [_]") submitted in support of Defendants' motion are annexed to the declaration of Garrett D. Kennedy, dated January 29, 2019, submitted herewith.

and e-mails demonstrate that he did no more than report the results of a study – something that, as a preclinical researcher, he did regularly. Second, SOX protects only complaints about violations of specifically enumerated ***securities*** laws, but Tonra's purported "complaints" do not even remotely touch on such matters. Third, Tonra did not reasonably believe he was objecting to unlawful conduct, nor could he have, since, *inter alia*, the purported unlawful conduct – possibly failing to report the study to the FDA – was speculative and had yet to occur (and never did).

Plaintiff's Section 740 claim – premised on the same "facts" as his SOX claim – fails as well. Section 740 prohibits retaliation against an employee who objects to an ***actual*** violation of law that creates a ***specific*** and ***substantial*** risk to public health. Here, Tonra never complained, much less about an "actual violation" of law. Even assuming *arguendo* that he "complained" (and he did not), there was no "substantial" risk to public health: tesevatinib was in clinical (*i.e.*, non-public) trials; all risks associated with tesevatinib were disclosed to trial subjects in Informed Consent Forms; and – as Tonra concedes in his e-mails – the animal study did not present any new safety risks.

Finally, Plaintiff's breach of contract claims also fail. Tonra's offer letter provides that, after 2011, he would be eligible for a bonus that "may be adjusted based on [Tonra's] performance as well as Company performance," *i.e.*, a discretionary bonus. New York law is clear: an employee cannot assert a cause of action where the "amount" of a bonus is discretionary. Moreover, Tonra's claim under New York Labor Law § 193 fails because that statute protects only wages, not bonuses with ***any*** discretionary element.

In short, Plaintiff's claims are manufactured and facially deficient. Defendants respectfully submit that they should be dismissed with prejudice, in their entirety.

STATEMENT OF FACTS[2]

I. Kadmon and Tonra, Generally

Kadmon is a biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics. (*See* Compl., ¶1.) Plaintiff was hired as an at-will employee by a subsidiary of Kadmon, in July 2011 as its Vice President, Preclinical Pharmacology.[3] (Compl., ¶16; *see* Ex. A.) Plaintiff remained so employed until his termination on September 28, 2017. (Compl., ¶¶64, 106, 124.)

Tonra was employed pursuant to an offer letter, dated July 25, 2011 (the "Offer Letter"). (*See* Ex. A.) Tonra was paid an annual salary, starting at $232,500 per year, which eventually increased to $300,000. (*Id.*; Compl., ¶39.) The Offer Letter also provided Tonra was eligible to receive a discretionary bonus, the amount of which, if any, was subject to both Tonra's and the Company's performance (following 2011). Specifically, the Offer Letter provides:

> <u>Guaranteed Bonus</u>: You will receive a guaranteed bonus equal to one third of your annual base salary. For calendar year 2011, this bonus will be subject to your performance. ***Subsequent to 2011, the bonus may be adjusted based on your performance as well as Company performance.***

(*See* Ex. A [emphasis added].)

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[2] As described herein, except as where otherwise noted, Defendants assume the truth of the factual allegations in the Complaint solely for purposes of this Motion.

[3] On a motion to dismiss, parties may rely on materials outside of the pleadings if incorporated into the complaint by reference or otherwise integral to the allegations in the complaint. *See Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 517 (S.D.N.Y. 2013). In addition, the Court may consider matters of public record, court records, and other matters of which judicial notice may be taken. *See, e.g., Mandavia v. Columbia Univ.*, 912 F. Supp. 2d 119, 121 (S.D.N.Y. 2012), *aff'd* 556 F. App'x 56 (2d Cir. 2014). The documents relied on by Defendants herein are incorporated by reference in the Complaint, and the Court may take judicial notice of information cited from governmental agencies.

Tonra claims here that he was not paid any bonus in 2011, 2014, 2015 or 2016.[4] (Compl., ¶¶1, 44.) He also claims that while he was paid a bonus in 2013, it was deficient because it "fell short of at least one-third of his base salary." (*Id.*)

II. Tonra's Whistleblower Allegations

a. The Biopharmaceutical Business, Generally

Kadmon is a biopharmaceutical company. Broadly, companies in this industry engage in the discovery and development of drug candidates based on a standard three-step protocol, with the ultimate goal of drug approval by the FDA. This protocol consists of: (i) first, researching, identifying and developing a potential molecule, compound or other pharmaceutical agent; (ii) next, pre-clinical testing; and (iii) finally, clinical trials. (*See* FDA, *The Drug Development Process* (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/default.htm.)

The first stage involves preliminary research and development ("R&D"), *i.e.*, identifying and developing molecules or compounds with potential pharmaceutical benefit, general safety and efficacy analysis, and related steps, including animal testing (but ***not*** human testing). (*See* FDA, *The Drug Development Process: Step 1* (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405382.htm.) As explained by the FDA: "At this stage in the process, thousands of compounds may be potential candidates for development as a medical treatment. After early testing, however, only a small number of compounds look promising and call for further study." (*Id.*)

At the second stage, pre-clinical (or "nonclinical") testing is conducted to support submission of an investigational new drug application ("IND") to the FDA. (*See* FDA, *The*

[4] While not clear from his allegations, it appears the bonus years referenced by Tonra relate to the year in which work was performed, and not the year in which the sought bonus was to be paid, *i.e.*, his 2016 "bonus" refers to a bonus payment with respect to 2016 and subsequently be paid in 2017. (Ex. A.)

Drug Development Process: Step 2 (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm.) Here, a researching company identifies a compound, potential dosage(s) and a risk profile, among other things, and conducts animal trials (not human) to support an IND. (*Id.*, *see also* 21 C.F.R. § 58.3(d) [testing includes in vitro and in vivo laboratory experimentation other than on "human subjects"].) While pre-clinical trials occur ***before*** FDA oversight, they must comply with FDA-proscribed standards. *See, e.g.*, 21 C.F.R. §§ 58.1, *et seq*.

The third stage – clinical testing – follows submission of an IND to the FDA. (*See* FDA, *The Drug Development Process: Step 3* (Jan. 4, 2018), https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm.) Clinical testing involves human trials – although supplemental animal testing may be conducted in parallel – and is subject to rigorous FDA oversight. (*See, e.g., id.*; *see also* 21 C.F.R. § 312.21.) Before beginning clinical testing, the researching company must provide the FDA with substantial information in support of the IND, as detailed in 21 C.F.R. §§ 312.23, *et seq*. This includes, in part, an "Investigator's Brochure" or "IB," which identifies certain required information. 21 C.F.R. § 312.55(a).

Once a clinical trial has started, the company must "keep [the FDA] informed of new observations . . . particularly with respect to adverse effects and safe use," which can be done through various means, including "periodically revised investigator brochures, reprints or published studies, reports or letters to clinical investigators, or other appropriate means." 21 C.F.R. § 312.55(b). Generally, the company provides annual updates on drug candidates (timed

based on the date of filing of the initial IND), provided that discovery of a previously unknown and significant safety risk may require earlier notification.[5] 21 C.F.R. §§ 312.32, 312.33.

b. <u>Tonra's Role and Alleged Whistleblower Claims</u>

As Kadmon's Vice President, Preclinical Pharmacology, Tonra had oversight responsibilities concerning pre-clinical research (*i.e.*, prior to submission of the IND to the FDA) (Compl., ¶31). These duties involved, *inter alia*, advancing projects from the R&D stage through pre-clinical testing and animal trials and, ultimately, into clinical testing. (Compl., ¶32.) Tonra also had certain responsibilities concerning drug candidates once clinical testing began, as he reviewed, revised and approved certain documents submitted to the FDA, including INDs, IBs, Informed Consent Forms (provided to clinical trial subjects, disclosing safety risks), and related materials. (*See* Compl., ¶68; Exs. B, C.)

Plaintiff alleges his employment was terminated because, on September 27, 2017, he provided Kadmon with the results of an animal study (the "Rat Study") concerning the drug candidate tesevatinib, also referred to as "KD019," which Tonra contends constituted "protected activity" under SOX and Section 740.[6] (Compl., ¶¶153-61.) By way of background, tesevatinib

[5] During the parties' January 8, 2019 conference, defense counsel indicated that IBs must be updated annually, or upon the discovery of new safety risks. To clarify, the governing regulations require only that informational updates regarding INDs be provided in such circumstances, but ***not*** updates to the IB itself. The updates can be made in various forms, including letters to the FDA or other "appropriate means." *See* 21 C.F.R. § 312.55(b); *see also* FDA, *Guidance for Industry and Investigators* (Dec. 2012), <u>https://www.fda.gov/downloads/Drugs/Guidances/UCM227351.pdf</u>.

[6] Plaintiff's Complaint references purported concerns that he allegedly raised about other molecules being researched by Kadmon, namely GLUT3 and ROCK1/ROCK2 ("panROCK") inhibitors. (Compl., ¶¶65-81.) While Defendants deny these allegations, Plaintiff's Causes of Action are based ***exclusively*** on his purported September

is a drug candidate in clinical testing (*i.e.*, human trials) for treatment of autosomal dominant and autosomal recessive polycystic kidney disease (respectively, "ADPKD" and "ARPKD"). (*See* Compl., ¶¶83.) In September 2017, clinical trials had been ongoing for years – the IND was first submitted in 2011 (*see* Ex. D) – at a number of well-respected research hospitals. (*See* NIH, *A Safety, Pharmacokinetic and Dose-Escalation Study of KD019 (Tesevatinib) in Subjects With ADPKD*, https://clinicaltrials.gov/ct2/show/NCT01559363?intr=tesevatinib&rank=6 [reflecting trials dating back to 2012].)

Tonra contends that in or about early 2017, following years of clinical testing, he commissioned a third-party, Crown Bioscience, to conduct the Rat Study, which examined study of tesevatinib's effects on rats. (Compl., ¶¶94-95.) The Rat Study sought to replicate a prior rat study by Dr. Ellis Avner, a researcher unaffiliated with Kadmon. (*Id.*)

On or about September 27, 2017, Plaintiff received the initial Rat Study results, although Crown Bioscience's report would not be finalized until months later. (*See* Compl., ¶94 ["all that remained was for [Crown Bioscience] to finalize a report"]; *see also* Ex. E [noting report was finalized on March 5, 2018, and amended on April 9, 2018].) These results were generally unremarkable: as described by Tonra in an e-mail to Kadmon personnel, they reflected no new safety concerns, and, while the Rat Study did not replicate the results of Dr. Avner's prior study, there were potential differentiating factors. (Compl., ¶¶94-99; Ex. B.)

Given the Rat Study's findings, Plaintiff expressly represented to his colleagues that he did ***not*** believe Kadmon needed to update its submissions to the FDA, since the safety concerns

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27, 2017 "complaint" regarding tesevatinib and the Rat Study. (*Id.*, ¶¶139-61.) As such, Tonra's purported other "concerns" are irrelevant and thus are not addressed here.

raised by the Rat Study already had been disclosed to the FDA. (Compl., ¶99 [noting information need only be included in "annual update"]; Ex. B.) Plaintiff expressly stated:

[redacted]

(Ex. B [emphasis added].) Rather than object to Tonra's e-mail, Kadmon personnel indicated that they wanted to "send these results" to additional researchers (including Dr. Avner) to "get their take on this" and better understand the results. (*Id.*)

On that same day, Tonra had been invited to attend a regularly scheduled meeting regarding testevatinib's IB. (Ex. C.) In an e-mail exchange in advance of this meeting with the Company's Senior Director, Regulatory Affairs, Tonra reiterated that there was no need to immediately report the Rat Study to the FDA:

> With regard to safety questions, ***I don't think the study adds any new safety concern that is not already mentioned***. Depending on the deadline for the regular IB update, ***we will incorporate the new data if the final report is ready in time***. With regard to the lack of efficacy, ***it is for John [Ryan, Kadmon's Chief Medical Officer] or others to decide*** . . . .

(*Id.* [emphasis added].) Indeed, Tonra not only acknowledged there was no need to immediately notify the FDA, but stated the Rat Study only needed to be included in the next update "***if the final report is ready in time***." (*Id.*) Stated otherwise, Tonra affirmed that if the final Rat Study report was not ready for the next annual update, Kadmon could wait ***another whole year*** before submitting it with Kadmon's subsequent annual update to the FDA. (*Id.*)

Given this background, Kadmon did not immediately report the Rat Study to the FDA – because it had no such obligation – but instead submitted such information in the ordinary course of its annual updates pursuant to 21 C.F.R. § 312.31(b).[7] Thus, following receipt of the Crown Bioscience's final report on March 5, 2018, Kadmon disclosed the Rat Study to the FDA ***that very same day*** via correspondence to the Director of the FDA's Division of Cardiovascular and Renal Products. (Ex. D.) This correspondence summarized the results of the Rat Study, including the (redundant and previously known) safety issues and efficacy results, and attached a copy of full study (on CD-ROM). (*Id*.)

Shortly thereafter, following a request for additional information from the FDA, Kadmon supplemented its submission and provided an amended version of the Rat Study. (*See* Ex. E.) Once again, on May 10, 2018, Kadmon provided the FDA with information about the Rat Study, this time as part of a routine Development Safety Update Report. (Ex. F, § 12.2.1.)

Critically, Tonra's SOX and Section 740 claims are premised on the theory that his employment was terminated because he raised concerns about tesevatinib in connection with the Rat Study. Assuming *arguendo* that Tonra's e-mails constitute him objecting to anything (and they do not), nowhere does Tonra allege that he complained or reasonably believed that he complained about any securities, bank or other investor-related fraud, as required by SOX, or

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[7] During the parties' January 8, 2019 court conference, defense counsel stated that Kadmon had updated its IB in early 2018 to reflect the results of the Rat Study. Defense counsel misspoke – Kadmon supplemented its ***IND*** with information regarding the Rat Study as part of its annual update in March 2018 (*see* Exs. D-F), as required; Kadmon did not update its ***IB*** in 2018, nor was it required to do so under any regulation, and it has not updated the IB since before Tonra's termination. *See* 21 C.F.R. §§ 312.32, 312.33, 312.55.

any practices constituting actual violations of law that create a substantial risk to public safety, as required by Section 740.[8]

ARGUMENT

I. Motion to Dismiss Standard

A motion to dismiss is proper where a complaint fails to "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Though the court must accept factual allegations as true, it is "not bound to accept as true a legal conclusion couched as a factual allegation." *Ashcroft*, 556 U.S. at 678 (*quoting Twombly*, 550 U.S. at 555). Moreover, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a viable claim. *Id*. Thus, a complaint must contain more than "'naked assertions' devoid of 'further factual enhancement.'" *Id*. (*quoting Twombly*, 550 U.S. at 557). Likewise, allegations which are no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not" survive

[8] As mentioned above, *see* note 6, *supra*, the Complaint references other molecules being researched by Kadmon – specifically, inhibitors of GLUT3 and of ROCK1 and ROCK2 ("panROCK"). However, Tonra bases no Causes of Action on any purported concerns raised about same. (*See* Compl., ¶¶139-61.) To the extent these allegations bear addressing, both the GLUT3 and panROCK inhibitors were in very preliminary R&D stages – such that Kadmon was still attempting to identify the operative molecule – and any testing was on animals. (*See* Compl., ¶80.) As such, unlike tesevatinib, no FDA reporting was required. Moreover, there is no threat to public safety, because any testing was on animals.

a motion to dismiss, *Twombly*, 550 U.S. at 555, as they are "not entitled to the assumption of truth" otherwise applied on a motions to dismiss. *Ashcroft*, 556 U.S. at 679.

II. Plaintiff Fails to State a Claim for Unlawful Retaliation Under SOX

Plaintiff contends his employment was terminated in retaliation for engaging in purported whistleblowing activity, in violation of Section 806 of SOX, 18 U.S.C. § 1514A. As detailed below, Plaintiff fails to state an actionable claim – indeed, his own allegations and e-mails expressly disprove his allegations – and, accordingly, his claims should be dismissed.

a. SOX, Generally

SOX protects from retaliation employees who:

> provide[s] information . . . regarding any conduct which the employee reasonably believes constitutes a violation of section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], any rule or regulation of the [SEC], or any provision of Federal law relating to fraud against shareholders, when the information . . . is provided to . . . a person with supervisory authority over the employee . . . .

18 U.S.C. § 1514A(a)(1)(C).

To state a *prima facie* SOX claim, an employee must show, *inter alia*, that he "engaged in protected activity . . . ." *Bechtel v. Admin. Rev. Bd., U.S. Dep't of Labor*, 710 F.3d 443, 447 (2d Cir. 2013). "To engage in an activity protected under SOX, a plaintiff '***must*** show that she held a reasonable belief that Defendants were engaged in conduct that violated one of the ***enumerated federal laws***' set forth in 18 U.S.C. § 1514A." *Diaz v. Transatlantic Reinsurance Co.*, 2016 WL 3568071, at *5 (S.D.N.Y. June 22, 2016) (*citing Ashmore v. CGI Grp. Inc.*, 138 F. Supp. 3d 329, 342 (S.D.N.Y. 2015)) (first emphasis added).

b. __Plaintiff Never Engaged in Protected Activity__

Plaintiff bases his SOX claim exclusively on his contention that he informed Kadmon of the results of the Rat Study on September 27, 2017 – which he purports constituted a "protected activity" – and that his employment was subsequently terminated. (Compl., ¶¶153-61.) Tonra further speculates that while no violation of law had occurred when he "complained," a future violation could occur if Kadmon ultimately did not disclose the Rat Study to the FDA (which, of course, Kadmon did disclose). (*Id*.)

Plaintiff's claim fails because he did not engage in any protected activity: (i) he never identified any unlawful conduct by Kadmon (there was none); (ii) his alleged "objections" do not relate to federal securities law; and (iii) he did not reasonably believe – either objectively or subjectively – that he complained about a violation of securities law.

i. Tonra Did Not Identify Conduct that He Believed to Be Illegal

It is well settled that while a SOX whistleblower need not "cite a code section he believes was violated" in an internal complaint, his "communications ***must*** identify the specific conduct that the employee ***believes to be illegal***." *Welch v. Chao*, 536 F.3d 269, 276-77 (4th Cir. 2008) (emphasis added) (*quoting Fraser v. Fiduciary Trust Co. Int'l*, 417 F. Supp. 2d 310 (S.D.N.Y. 2006) and *citing Bechtel Constr. Co. v. Sec'y of Labor*, 50 F.3d 926 (11th Cir. 1995)). As explained by one court – and affirmed by the Second Circuit:

> General inquiries do not constitute protected activity. In order for the whistleblower to be protected by SOX, the reported information ***must*** have a ***certain degree of specificity***. A whistleblower must state ***particular concerns*** which, at the very least, ***reasonably identify a respondent's conduct*** that the complainant believes to be illegal.

Fraser v. Fiduciary Trust Co. Int'l, 2009 WL 2601389, at *5 (S.D.N.Y. Aug. 25, 2009), *aff'd*, 396 F. App'x 734 (2d Cir. 2010) (emphasis added).

Here, Tonra's SOX claim rests on the contention that he engaged in a "protected activity" by "communicat[ing] the final results of the tesevatinib" Rat Study to Kadmon. (Compl., ¶¶94, 153-61.) Tonra's e-mails and allegations speak for themselves: they do not object to ***any unlawful practice***, much less identify an unlawful practice with "specificity" or any "particular concerns." *Fraser*, 2009 WL 2601389, at *5. Rather, a facial reading of these e-mails and Tonra's Complaint reveals that he did no more than relay the results of the Rat Study. (Compl., ¶¶95-96; Exs. B, C.)

To the extent he contends there was some need to report the Rat Study to the FDA, this is unavailing. In the first instance, merely relaying a potential future reporting obligation does not equate to identifying unlawful conduct with any "degree of specificity," as required. *Fraser*, 2009 WL 2601389, at *5. Beyond this, Tonra acknowledges there was no urgency in reporting the results: he concedes that no update was required until the next "annual update" (Compl., ¶99), which is echoed in his e-mails, wherein he states that notifying the FDA could wait until the next annual report or – if Crown BioScience's report was not finalized then – "until the next scheduled document updates" a year later (Exs. B, C).

In short, Tonra's allegations do not, and cannot, constitute whistleblowing activity, nor can one possibly reads his e-mails as raising any concerns about unlawful conduct.

ii. Plaintiff Did Not Object to Conduct Relating to Federal Securities Law

It is axiomatic law that to be a SOX "whistleblower," an employee's objection must relate to conduct which he reasonably believes "violat[es] section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders." 18 U.S.C. § 1514A(a)(1). "[A] whistleblower must plausibly allege that he 'reported

information based on a reasonable belief that the employer violated ***one of the enumerated provisions*** set out in the statute.'" *Lawrence v. I.B.M. Corp.*, 2017 WL 3278917, at *10 (S.D.N.Y. Aug. 1, 2017) (*quoting Nielsen v. AECOM Tech. Corp.*, 762 F.3d 214, 221 n.6 (2d Cir. 2014)).

"A plain reading of the relevant . . . SOX provisions clearly show that the conduct reported by a whistleblower ***must deal with a violation of not any federal law, but of federal securities law*** . . . ." *Diaz*, 2016 WL 3568071, at *5 (emphasis added). Courts have expressly rejected the proposition "that a whistleblower's complaint 'need not even approximate specific elements of the enumerated provisions allegedly violated.'" *Lawrence*, 2017 WL 3278917, at *10 (*quoting Nielsen*, 762 F.3d at 221, n.6). Thus, absent an alleged violation of federal securities law, a plaintiff's claim is deficient. *Diaz*, 2016 WL 3568071, at *5 (dismissing claim where plaintiff did not object to alleged violations of federal securities law).

Here, even accepting as true that Plaintiff raised internal "complaints" (which, as detailed above, he did not), it is indisputable that he did not object to any purported violation of ***federal securities law***. Plaintiff's entire SOX claim is based on the proposition that he reported the results of the Rat Study to the Company, and indicated that it should be disclosed to the FDA at some point in the future – either with the next annual update to the FDA or the subsequent one. (Compl., ¶¶153-61; Exs. B-C.) Nothing even tangentially touches on any alleged "violation of section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders." 18 U.S.C. § 1514A(a)(1).

Simply put, a complaint – even about a violation of federal law unrelated to securities law (and to be clear, there was none) – is insufficient under SOX, and courts dismiss claims in such

circumstances. *See, e.g., Diaz*, 2016 WL 3568071, at *5 (dismissing claim where no complaint that defendants "provid[ed] false or fraudulent information to shareholders or the public"); *Gallas v. Med. Ctr. of Aurora*, 2017 WL 2222626, at *6 (Dept. of Labor SAROX Apr. 28, 2017) (dismissing SOX claim alleging violations of HIPAA and similar healthcare laws, since they "did not implicate any of the six enumerated categories of protected activity under the SOX"). The result here should be no different.

iii. Plaintiff Did Not Reasonably Believe Kadmon Violated Securities Law

While a SOX plaintiff need not complain of an actual violation of securities law, he must "reasonably believe[]" the complained of conduct "constitutes a violation" of the enumerated securities laws. Tonra's allegations and e-mails affirm that he did ***not*** believe Kadmon had violated securities law.

As explained by the Second Circuit:

> [Section] 1514A's critical focus is on whether the employee reported conduct that ***he or she reasonably believes constituted a violation of federal law***. A reasonable belief contains both subjective and objective components. That is to say, a plaintiff must show not only that he believed that the conduct constituted a violation, but also that a reasonable person in his position would have believed that the conduct constituted a violation.

Nielsen, 762 F.3d at 221 (citations and internal quotations omitted, emphasis added).

Tonra cannot demonstrate he reasonably believed Kadmon violated any securities law. ***First***, it was not "objectively reasonable for [Tonra] to believe" he had reported a violation of the federal securities law, based on his allegations and the e-mails. *Nielsen*, 762 F.3d at 222 (affirming dismissal where plaintiff failed to plead facts sufficient to support "objectively reasonable" belief that complaint related to securities fraud). Objective reasonableness is "evaluated based on the knowledge available to a reasonable person in the same factual

circumstances with the same training and experience as the aggrieved employee." *Leviege v. Vodafone U.S., Inc.*, 2017 WL 628506, at *5 (Dept. of Labor SAROX Feb. 1, 2017).

Here, it was not "objectively reasonable" for a person with Tonra's "training and experience" to believe he complained of any violation of federal securities law. Tonra – a clinician with a Ph.D. and over twenty years of professional experience (Compl., ¶20) – sent e-mails relaying the results of the Rat Study to colleagues, something that was entirely consistent with his routine duties of overseeing preclinical trials (*see* Compl., ¶¶32-33; Exs. B, C). It is absurd to suggest a person with this background and routine duties believed that – in this one (very convenient) instance – he objected to securities fraud ***without ever once mentioning any purported securities law violation in the relevant communications***. This is because he did not "reasonably believe" he was objecting to bank or wire fraud, shareholder fraud, or anything else of the sort, nor do his pleadings or e-mails support as much.

Moreover, the objective reasonableness of a complaint is measured as of "the time [the plaintiff] reported the perceived illegal behavior," not based on subsequent information. *Wiggins v. ING U.S., Inc.*, 2015 WL 8779559, at *4 (D. Conn. Dec. 15, 2015). Here, Tonra's allegations are that, at some point in the ***future***, he thought Kadmon ***might*** fail to submit the Rat Study to the FDA; because this is based on future events – not what was known at the time of the "complaint" – his purported "complaint" cannot be objectively reasonable.

Second, Tonra did not "subjectively believe" that he "complained" about any securities law violation, a fact proven by his allegations and e-mails. "[S]ubjective reasonableness requires that the employee actually believes the conduct being complained of constitutes a violation of pertinent law." *Leviege*, 2017 WL 628506, at *5 (*citing Day v. Staples*, 555 F.3d 42, 54 (1st Cir. 2009); *Harp v. Charter Commc'ns, Inc.*, 558 F.3d 722, 723 (7th Cir. 2009)). Here, Tonra's e-

mails, on their face, do not allege any "violation" of federal securities law, nor suggest improper conduct by Kadmon; rather, they reflect Tonra, a researcher, bringing the Rat Study to Kadmon's attention – the very essence of his duties. (Exs. B, C.)

Moreover, Plaintiff's own allegations demonstrate that when he raised the Rat Study, he did not subjectively believe Kadmon had violated any law. Tonra alleges, at most, that he believed there was a chance that in the future Kadmon would not disclose the Rat Study to the FDA (even though it did so). (Compl., ¶¶110-13.) Simply put, Tonra could not believe he was objecting to any violation of law because by his own pleadings ***none had yet occurred*** (nor would it ever).[9]

III. Plaintiff's New York Labor Law §§ 215 and 740 Claims Are Deficient

Plaintiff contends he was subject to retaliation under Section 740 and New York Labor Law § 215 ("Section 215"). Like his SOX claim, these claims are premised on his reporting of the Rat Study to Kadmon. These claims are facially defective: (i) Section 740 requires that Plaintiff demonstrate that he objected to an actual violation of law creating a substantial risk to public safety, which he never did; and (ii) Section 215 is preempted by his Section 740 claim.

a. Plaintiff Fails to State an Actionable Section 740 Claim

Section 740 prohibits retaliation against an employee who objects to an ***actual*** violation of law that "causes a ***substantial*** and ***specific*** danger to the ***public health or safety***." *See*

[9] As noted above in footnote 6, Plaintiff's Complaint cites, references, but asserts no causes of action regarding, other molecules being researched by Kadmon, namely GLUT3 and ROCK1/ROCK2 inhibitors. (Compl., ¶¶65-81.) To the extent Plaintiff asserts SOX claims regarding these molecules, they are deficient because: (i) he does not allege making any complaint; and (ii) even if he did, nothing touches on securities fraud. To this end, these molecules were at early R&D phases and, thus, did not require any FDA (or other) disclosures, so there is no possible argument Kadmon had any obligation to submit updated materials regarding these molecules.

Nadkarni v. N. Shore-Long Island Jewish Health Sys., 21 A.D.3d 354, 355 (2d Dep't, 2005) (emphasis added). That an employee holds a "good faith, reasonable belief that a violation occurred is insufficient," *id.*, as is "mere speculation" that conduct could create a "substantial and specific danger," *Barber v. Von Roll U.S.A., Inc.*, 2015 WL 5023624, at *14 (N.D.N.Y. Aug. 25, 2015).

Plaintiff has failed to meet Section 740's exacting standard. First, as noted above, Tonra did not object to or raise any internal complaints about anything. (*See* Section II.b.i, *supra.*)

Second, he has not alleged any ***actual*** violation of law. *Nadkarni*, 21 A.D.3d at 355. Indeed, it is not clear what possible violation he could allege, as the only purported "violation" is the hypothetical possibility Kadmon might someday fail to disclose the Rat Study to the FDA – which cannot constitute a complaint about an "actual" violation.

Third, Tonra has not alleged that Kadmon's conduct created any "substantial and specific risk to public health or safety" (because it did not). NYLL § 740. As alleged, Tonra "complained" about the Rat Study, but there could be no "substantial and specific risk to public health or safety" because, *inter alia*: (i) the safety risks reported in the Rat Study were already known and disclosed to the FDA, as conceded by Plaintiff (Exs. B, C); (ii) Tonra considered any risks raised by the Rat Study so nominal that they did not need to be reported to the FDA for months (or longer); and (iii) there was no "public" health risk, as tesevatinib was in clinical trials, where all trial subjects executed Informed Consent Forms, as required by the FDA. *See, e.g., Lloyd v. Cardiology & Internal Med. of Long Island, PLLC*, 847 N.Y.S.2d 902 (Sup. Ct., Nassau Cnty. 2007) (where conduct caused risk to only two patients, did not constitute "public" risk); *Kern v. DePaul Mental Health Servs., Inc.*, 152 A.D.2d 957 (4th Dep't 1989) (neglect of a single patient "did not threaten health or safety of the public"). Indeed, courts considering

Section 740 claims apply an exacting threshold to the "public safety" examination and routinely dismiss claims even where some risk is posed, if such is not immediate or sufficiently severe, and the result here should be no different. *See, e.g., Cotrone v. Consol. Edison Co. of N.Y., Inc.*, 50 A.D.3d 354 (1st Dep't 2008) (dismissing claim where tanker trucks with hazardous materials were left unattended on a public street as insufficient under Section 740).

Based on the above, Defendants respectfully submit that Plaintiff's Section 740 Claim should be dismissed.[10]

b. <u>Plaintiff's Section 740 Claim Preempts his Section 215 Claim</u>

Plaintiff's Section 215 claim is preempted by his Section 740 claim. Section 740(7) provides that "the institution of an action in accordance with [Section 740] shall be deemed a waiver of the rights and remedies available under any other . . . law, rule or regulation." This waiver precludes a plaintiff from bringing other state law whistleblowing claims based on the same facts. *Collette v. St. Luke's Roosevelt Hosp.*, 132 F. Supp. 2d 256, 274 (S.D.N.Y. 2001). Here, Plaintiff's Section 740 and Section 215 claims are premised on the exact same factual allegations (*compare* Compl., ¶¶139-147 *with* ¶¶148-152) and, thus, his Section 215 is preempted.

[10] Like his SOX claim, Plaintiff's Section 740 Cause of Action does not address any purported complaints raised regarding GLUT3 and ROCK1/ROCK2. (Compl., ¶¶139-47.) To the extent such needs to be addressed, Tonra cannot state a claim under Section 740 with respect to these molecules for the very simple reason that none were in – or anywhere close to – human trials, and thus there was no "specific and serious" risk to public safety, nor does he allege any actual violation of law with respect to same.

IV. <u>Plaintiff's Claims for Breach of Contract and Related Claims Are Deficient</u>

Tonra seeks recovery of purportedly unpaid bonuses under his Offer Letter, alleging claims pursuant to Section 193 of the New York Labor Law and common law claims for breach of contract. These claims fail as a matter of law.

a. The Sought Bonus Does Not Constitute <u>"Wages" Under the New York Labor Law</u>

Plaintiff's Third Cause of Action seeks recovery under Section 193 of the New York Labor Law ("Section 193") for purportedly unpaid bonuses. However, Section 193 governs only "wages," as defined under the New York Labor Law, and precedent is abundantly clear that bonuses like those sought here are not "wages."

Broadly, Section 193(1) provides that "[n]o employer shall make any deduction from the wages of an employee," except in enumerated circumstances. For purposes of the New York Labor Law, "[c]ourts have construed this statutory definition [of wages] as ***excluding*** certain forms of 'incentive compensation' that are more in the nature of a profit-sharing arrangement and are both contingent and dependent, ***at least in part***, on the financial success of the business enterprise." *Truelove v. Ne. Capital & Advisory, Inc.*, 95 N.Y.2d 220, 223-24 (N.Y. 2000) (emphasis added). The "dispositive factor" is "whether the compensation is vested and mandatory as opposed to discretionary and forfeitable." *Truelove v. Ne. Capital & Advisory Inc.*, 268 A.D.2d 648, 649 (3d Dep't 2000), *aff'd*, 95 N.Y.2d 220 (N.Y. 2000) (citation omitted).

Truelove and its progeny hold that where a bonus is contingent – whether "in part" or whole – on company performance or other factors outside an employee's control, it is not "wages" under Section 193, and any such claim should be dismissed. *See Truelove*, 95 N.Y.2d at 223-24 (where bonus plan depended on employer profitability, bonus was not "wages"); *Duffy v. RMSCO, Inc.*, 34 A.D.3d 1285, 1286 (4th Dep't 2006) (not wages where bonus depended, "at

least in part," on company performance); *Beach v. Touradji Capital Mgmt., LP*, 2014 WL 840409, at *3 (Sup. Ct. N.Y. Cnty. Feb. 26, 2014) (not "wages" where bonus amount was contingent on other workers' performance); *Barber v. Deutsche Bank Sec., Inc*., 103 A.D.3d 512, 514 (1st Dep't 2013) (not "wages" where bonus depended on amount of payments to other employees).

Here, the Offer Letter unequivocally states that "[s]ubsequent to 2011, the bonus ***may be adjusted based on your performance as well as Company performance***." (Ex. A; Tonra's purported 2011 bonus claim is time-barred, *see* Section III.b.ii, below.) Thus, any bonus is contingent on factors outside of Tonra's control – namely "Company performance" – and his Section 193 claim must be dismissed.

b. Plaintiff's Breach of Contract of Claims Fail as a Matter of Law

i. The Sought Bonuses Are Discretionary

Plaintiff contends he is owed unpaid bonuses for certain years during his employment, claiming such bonuses were "guaranteed" under his Offer Letter. (Compl., ¶¶125-29.) This claim is deficient: the Offer Letter is clear that the bonuses at issue are discretionary, and it is well-settled under New York law that "[a]n employee cannot establish that an employer breached a contract to pay a particular amount of bonus compensation where ***the employer retains discretion regarding the amount of bonus compensation to be awarded***." *Arrouet v. Brown Bros. Harriman & Co*., 2005 WL 646111, at *4 (S.D.N.Y. Mar. 18, 2005) (emphasis added). *See also Namad v. Salomon Inc*., 74 N.Y.2d 751, 753 (N.Y. 1989) (dismissing claim for bonus where "amount" was in discretion of employer); *Grieve v. Barclays Capital Sec. Ltd*., 1999 WL 1680654, at *4 (Sup. Ct., N.Y. Cnty. Sept. 10, 1999) ("An employee has no enforceable right to compensation under a discretionary compensation or bonus plan.").

The Offer Letter provides that any bonus which Plaintiff could receive "***may be adjusted based on [Tonra's] performance as well as Company performance***." (Ex. A.) Thus, Kadmon retained discretion over the "amount of bonus compensation to be awarded," *Arrouet*, 2005 WL 646111, at *4: among other considerations, the Offer Letter provides no criteria for determining the amount of any adjustment, no parameters for the weight to be given to any factor in determining bonus amount, if any, and no limitation on how much any bonus can be adjusted. By its terms, the "amount of the bonus," if any, was necessarily in the Company's discretion, and Plaintiff's breach of contract claim thus is facially deficient.

ii. The 2011 Bonus Claim Is Barred by the Statute of Limitations

Plaintiff purports Kadmon breached his Offer Letter by failing to pay him a bonus for 2011. (Compl., ¶1.) This claim is untimely. New York law provides for a six-year statute of limitations for breach of contract claims. C.P.L.R. § 213(2); *see, e.g., Gross v. 420 E. 72nd St. Tenants Corp.*, 864 N.Y.S.2d 863, 865 (Sup. Ct., N.Y. Cnty. 2008). Under the Offer Letter, his bonus, if any, was due by no later than March 15 of the year after it was earned. (Ex. A.) As such, any 2011 bonus was due by no later than March 15, 2012. However, Plaintiff filed his Complaint on October 2, 2018 (ECF No. 1), thus extending the statute of limitations period to only October 2012. Accordingly, this claim is untimely.

iii. Plaintiff's Breach of the Covenant of Good Faith and Fair Dealing Should Also Be Dismissed

Tonra asserts a claim for breach of the implied covenant of good faith and fair dealing. Where claims for breach of contract and breach of the implied covenant are pled based on the same facts, the latter is duplicative and subject to dismissal. *Canstar v. J.A. Jones Const. Co.*, 212 A.D.2d 452, 453 (1st Dep't 1995). Such is the case here. (*Compare* Compl., ¶¶125-29 *with id.*, ¶¶130-33.)

CONCLUSION

Based on the foregoing, Defendants respectfully request that the Court grant its Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

Dated: New York, New York
January 29, 2019

DLA PIPER LLP (US)

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CERTIFICATION PURSUANT TO HON. JOHN G. KOELTL'S INDIVIDUAL PRACTICE RULE 2(D)

In accordance with Hon. John G. Koeltl's Individual Practice Rule 2(D), I hereby certify that this Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiff's Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) contains 6,925 words, including footnotes but excluding the caption, tables, counsel's signature block, and this certification, as counted by Microsoft Word, and that the Memorandum complies with Local Civil Rule 11.1 of the Southern District of New York and the Court's Individual Rules of Practice.

Dated: January 29, 2019

By: *_/s/ Garrett D. Kennedy_*
Garrett D. Kennedy